

- 41 -

**I Claim:**

1. A method for detecting a kallikrein 8 polypeptide associated with ovarian cancer in a patient comprising:  
5       (a) obtaining a sample from a patient;  
         (b) detecting in the sample kallikrein 8 polypeptide; and  
         (c) comparing the detected amounts with amounts detected for a standard.
- 10   2. A method for diagnosing and monitoring ovarian cancer in a subject comprising detecting in a sample from the subject a kallikrein 8 polypeptide.
3. A method of detecting ovarian cancer in a patient, the method comprising comparing:  
         (a) levels of a kallikrein 8 polypeptide in a sample from the patient; and  
         (b) normal levels of expression of kallikrein 8 polypeptide in a control sample, wherein a significant  
15       difference in levels of kallikrein 8 polypeptide, relative to the corresponding normal levels, is indicative of ovarian cancer.
4. A method for monitoring the progression of ovarian cancer in a patient, the method comprising: (a) detecting in a sample from the patient at a first time point, a kallikrein 8 polypeptide; (b) repeating  
20       step (a) at a subsequent point in time; and (c) comparing levels detected in steps (a) and (b), and thereby monitoring the progression of ovarian cancer.
5. A method for determining in a patient whether ovarian cancer has metastasized or is likely to metastasize in the future, the method comprising comparing (a) levels of a kallikrein 8 polypeptide in  
25       a patient sample; and (b) normal levels or non-metastatic levels of a kallikrein 8 polypeptide, in a control sample wherein a significant difference between the levels of expression in the patient sample and the normal levels or non-metastatic levels is an indication that the ovarian cancer has metastasized.
- 30   6. A method for assessing the aggressiveness or indolence of ovarian cancer comprising comparing: (a) levels of expression of a kallikrein 8 polypeptide in a patient sample,; and (b) normal levels of expression of the kallikrein 8 polypeptide, in a control sample, wherein a significant difference between the levels in the patient sample and normal levels is an indication that the cancer is aggressive or indolent.  
35
7. A method for assessing the potential efficacy of a test agent for inhibiting ovarian cancer in a patient, the method comprising comparing: (a) levels of a kallikrein 8 polypeptide in a first sample obtained

- 42 -

5 from a patient and exposed to the test agent, and (b) levels of the kallikrein 8 polypeptide in a second sample obtained from the patient, wherein the sample is not exposed to the test agent, wherein a significant difference in the levels of expression of the kallikrein 8 polypeptide in the first sample, relative to the second sample, is an indication that the test agent is potentially efficacious for inhibiting ovarian cancer in the patient.

8. A method of claim 7 wherein the first and second samples are portions of a single sample obtained from the patient.
- 10 9. A method of claim 7 wherein the first and second samples are portions of pooled samples obtained from the patient.
- 15 10. A method of assessing the efficacy of a therapy for inhibiting ovarian cancer in a patient, the method comprising comparing: (a) levels of a kallikrein 8 polypeptide in a first sample obtained from the patient, and (b) levels of the kallikrein 8 polypeptide in a second sample obtained from the patient following therapy, wherein a significant difference in the levels of expression of the kallikrein 8 polypeptide in the second sample, relative to the first sample, is an indication that the therapy is efficacious for inhibiting ovarian cancer in the patient.
- 20 11. A method of selecting an agent for inhibiting ovarian cancer in a patient the method comprising (a) obtaining a sample comprising cancer cells from the patient; (b) separately exposing aliquots of the sample in the presence of a plurality of test agents; (c) comparing levels of kallikrein 8 polypeptide in each of the aliquots; and (d) selecting one of the test agents which alters the levels of kallikrein 8 polypeptide in the aliquot containing that test agent, relative to other test agents.
- 25 12. A method of inhibiting ovarian cancer in a patient, the method comprising (a) obtaining a sample comprising cancer cells from the patient; (b) separately maintaining aliquots of the sample in the presence of a plurality of test agents; (c) comparing levels of kallikrein 8 polypeptide in each of the aliquots, and (d) administering to the patient at least one of the test agents which alters the levels of kallikrein 8 polypeptide in the aliquot containing that test agent, relative to other test agents.
- 30 13. A method of assessing the ovarian cancer cell carcinogenic potential of a test compound, the method comprising: (a) maintaining separate aliquots of ovarian cancer cells in the presence and absence of the test compound; and (b) comparing expression of a kallikrein 8 polypeptide in each of the aliquots, and wherein a significant difference in levels of kallikrein 8 polypeptide in the aliquot maintained in the presence of the test compound, relative to the aliquot maintained in the absence of the test compound, is an indication that the test compound possesses ovarian cancer cell carcinogenic potential.
- 35

- 43 -

14. A method of any preceding claim wherein the patient sample comprises serum obtained from the patient.
- 5 15. A method of any preceding claim wherein the kallikrein 8 polypeptide is detected using antibodies that bind to a kallikrein 8 polypeptide or part thereof.
16. A method of claim 15 wherein the antibodies are used in an immunoassay.
- 10 17. A method as claimed in any preceding claim which further comprises detecting one or more of human stratum corneum chymotryptic enzyme (HSCCE), kallikrein 2, kallikrein 3, kallikrein 4, kallikrein 5, kallikrein 6, kallikrein 9, kallikrein 10, kallikrein 11, CA125, CA15-3, CA72-4, CA19-9, OVX1, lysophosphatidic acid (LPA), creatin-kinase BB, haptoglobin alpha, prostatic acid phosphatase, osteopontin, and carcinoembryonic antigen (CEA).
- 15 18. A method for screening a subject for ovarian cancer comprising:
- (a) incubating a biological sample from the subject with a first antibody specific for hK8 which is directly or indirectly labeled with a detectable substance, and a second antibody specific for hK8 which is immobilized;
  - 20 (b) separating the first antibody from the second antibody to provide a first antibody phase and a second antibody phase;
  - (c) detecting the detectable substance in the first or second antibody phase thereby quantitating hK8 in the biological sample; and
  - (d) comparing the quantitated hK8 with levels for a predetermined standard.
- 25 19. An *in vivo* method for imaging ovarian cancer comprising:
- (a) injecting a patient with an agent that binds to a kallikrein 8 polypeptide, the agent carrying a label for imaging the ovarian cancer;
  - (b) allowing the agent to incubate *in vivo* and bind to a kallikrein 8 polypeptide associated with the ovarian cancer; and
  - 30 (c) detecting the presence of the label localized to the ovarian cancer.
20. A method as claimed in claim 19 wherein the agent is an antibody which recognizes a kallikrein 8 polypeptide.
- 35 21. A method as claimed in claim 19 or 20 wherein the label is a radiolabel, fluorescent label, nuclear magnetic resonance active label, positron emitting isotope detectable by a positron emission tomography ("PET") scanner, chemiluminescer, or enzymatic marker.

- 44 -

22. A kit for carrying out a method as claimed in any preceding claim.
23. A kit for assessing whether a patient is afflicted with ovarian cancer, the kit comprising reagents that  
5 specifically bind with kallikrein 8 polypeptides.
24. A kit for assessing the suitability of each of a plurality of agents for inhibiting ovarian cancer in a  
patient, the kit comprising: (a) the plurality of agents; and (b) reagents for detecting a kallikrein 8  
10 polypeptide.
25. A kit as claimed in claim 23 or 24 wherein the reagents are antibodies that specifically bind with  
protein or protein fragments corresponding to a kallikrein 8 polypeptide.
26. A medium for holding instructions for performing a method for determining whether a patient has  
15 ovarian cancer or a pre-disposition to ovarian cancer, comprising determining the presence or absence  
of a kallikrein 8 polypeptide, and based on the presence or absence of the kallikrein 8 polypeptide,  
determining whether the patient has ovarian cancer or a pre-disposition to ovarian cancer, and  
optionally recommending treatment for the ovarian cancer or pre-ovarian cancer condition.
- 20 27. A method in an electronic system and/or in a network for determining whether a subject has ovarian  
cancer or a pre-disposition to ovarian cancer associated with a kallikrein 8 polypeptide comprising  
determining the presence or absence of a kallikrein 8 polypeptide, and based on the presence or  
absence of the kallikrein 8 polypeptide, determining whether the subject has ovarian cancer or a pre-  
25 disposition to ovarian cancer, and optionally recommending treatment for the ovarian cancer or pre-  
ovarian cancer condition.
28. A method of treating a patient susceptible to, or having a cancer that expresses a kallikrein 8  
polypeptide comprising administering to the patient an effective amount of antibodies that bind  
30 specifically to a kallikrein 8 polypeptide.
29. A method of inhibiting the growth of tumor cells expressing a kallikrein 8 polypeptide, comprising  
administering to a patient antibodies which bind specifically to a kallikrein 8 polypeptide in amounts  
effective to inhibit growth of the tumor cells.
- 35